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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/677,321

10/03/2003

Herbert Andre Jansen

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EXAMINER

BOLES, SAMEH RAAFAT

ART UNIT

PAPER NUMBER

3775

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/677,321	JANSEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SAMEH BOLES	3775	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 1-3 and 5-8 is/are pending in the application.
- 5a) Of the above claim(s) 1 and 2 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 3 and 5-8 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 7/13/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

According to the Amendment filed on May 27, 2011, claims 1-2 are withdrawn, claim 3 is amended, claim 4 is cancelled and claims 3, and 5-8 are examined in this office action.

### **Claim Objections**

1. Claim 3 is objected to because of the following informalities:

The limitation of "an intramedullary" in lines 9 and 28 should be replaced by (the intramedullary). Appropriate correction is required.

2. Claim 7 is objected to because of the following informalities:

The limitation of "a surface" in lines 4 should be replaced by (the surface). Appropriate correction is required.

3. Furthermore, examiner proposing deleting the limitation of word "comprising" in line 4 of claim 3.

### **Claim Rejections - 35 USC § 112**

- a. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 3 recites the limitation "the surface" in line 20. There is insufficient antecedent basis for this limitation in the claim.
2. Claim 3 recites the limitation "the tracking" in 23. There is insufficient antecedent basis for this limitation in the claim.

### **Claim Rejections - 35 USC § 103**

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 3, 5-6, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis (US. Pat. No. 5171248) in view of Brosseau et al. (US. Pat. No. 6450978 B1).

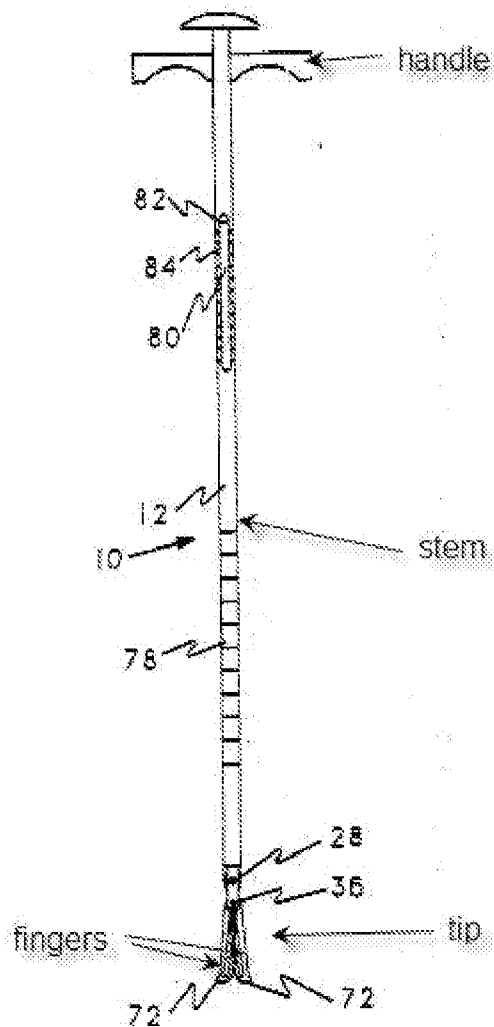
Ellis discloses an apparatus (Fig. 3) capable of obtaining an axis of an intramedullary canal of an exposed bone comprising: a stem portion (12) having a leading end insertable in an intramedullary canal of the bone through an opening in the bone, and being adapted to be handled by a following end thereof (see modified figure 3 below); and a tip portion (see modified figure 3 below) at the leading end of the stem portion, the tip portion having two fingers (32 and 34, Fig. 5) actuatable (see Figs. 1-3) from the following end of the stem portion to extend radially (Fig. 3) from the stem portion (12) with tips (72) of the fingers (32 and 34) being equidistantly spaced (Fig. 3) from the stem portion and capable to center the leading end of the stem portion in the intramedullary canal by contacting the surface of the intramedullary canal, wherein the fingers are pivotally mounted to one another (col. 3, lines 19-23), wherein the fingers are biased to be retracted radially (Fig. 1), so as to facilitate an insertion of the stem portion in the intramedullary canal. The stem portion is graduated (78) on an outer surface thereof to indicate a depth of insertion of the stem portion in the intramedullary canal (Fig. 3).

Ellis fails to disclose a position tracking system and a computer-assisted surgery system comprising a detectable device trackable in space; the tracking system for tracking the detectable device; and the computer-assisted surgery system for determining at least an orientation of the apparatus, and for digitizing an intramedullary canal of the bone from the orientation of the apparatus when the fingers are actuated into contacting the surface of the intramedullary canal, the computer-assisted surgery system comprising a user interface for outputting data related to the axis of the intramedullary canal from the tracking of the detectable device and from the digitization of the intramedullary canal.

Brosseau teach a surgical tool (20, Figs. 1 and 2) with a combination with a position tracking system (22, Fig. 1) and a computer-assisted surgery system (10, Figs. 1 and 3) comprising a detectable device trackable (42, Fig. 2) secured to the surgical device (20) in space, wherein the tracking system (22) for tracking the detectable device (42) (col. 5, lines 24-27); and the computer-assisted surgery system (10) for determining at least an orientation of the apparatus (abstract), and capable of digitizing an intramedullary canal of the bone from the orientation of the apparatus when the fingers are actuated into contacting the surface of the intramedullary canal, the computer-assisted surgery system comprising a user interface such as a display monitor (18, Figs. 1 and 3) capable of outputting data related to the axis of the intramedullary canal from the tracking of the detectable device and from the digitization of the intramedullary canal.

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It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to modify the apparatus of Ellis with a combination with a position tracking system and a computer-assisted surgery system comprising a detectable device trackable in space and a user interface for outputting data in view of Brosseau for effectively and accurately tracking the position of the apparatus with respect to the anatomy bone.

**FIG. 3**

3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis in view of Brosseau and further in view of Kuslich et al. (US. pat. No. 6620162).

Ellis in view of Brosseau fails to teach a flared adapter slidably mounted on the stem portion, the flared adapter being flared toward the following end of the stem portion to engage with a surface of the intramedullary canal at the opening of the intramedullary canal, to center the stem portion in the intramedullary canal.

Kuslich teaches a flared adapter (100, fig. 5) slidably mounted on the stem portion (14), the flared adapter being flared toward the following end of the stem portion to engage with a surface of an opening of the operation site (96) (Fig. 5), and capable to center the stem portion in the opening and to control the insertion depth of the stem (col. 7, lines 62-67).

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to modify the combination device of Ellis in view of Brosseau with a flared adapter further in view of Kuslich for effectively controlling the insertion depth of the stem.

### **Response to Arguments**

Applicant's arguments with respect to claims have been fully considered but they are not persuasive.

Applicant argues that "the medullary caliper of Ellis is strictly limited to being used to measure a width of the intramedullary canal and a depth of insertion. The caliper of Ellis is strictly a mechanical device"; applicant further argues that "As for

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Brosseau, the Applicants acknowledge that Brosseau teaches computer- assisted surgery. However, the present application clearly teaches and now claims the use of an apparatus to obtain an axis of an intramedullary canal for its subsequent tracking.

Accordingly, combination claim 3 now features limitations pertaining to a user interface that produces data related to an axis of the intramedullary canal, which axis is obtained from the insertion of the apparatus in the intramedullary canal, and from a tracking of the detectable device on the apparatus. This is not taught in any way by Ellis or Brosseau. Both these references fail to teach the insertion of a tool inside the intramedullary canal to provide an output related to a tracking of the axis of the intramedullary canal.”

Examiner respectfully disagrees since it is noted that “while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Also, since a claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Applicant argues that the medullary caliper of Ellis is not described as being usable in any way with a computer-assisted surgery system.



In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, it would have been obvious to a person of ordinary skill in the art at the time of the invention was made to modify the apparatus of Ellis with a combination with a position tracking system and a computer-assisted surgery system comprising a detectable device trackable in space and a user interface for outputting data in view of Brosseau for effectively and accurately tracking the position of the apparatus with respect to the anatomy bone.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sameh R Boles whose telephone number is (571)270-5537. The examiner can normally be reached on WORK SCHEDULE.

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Thomas Barrett, at 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700 Workgroup D Inquiries@uspto.gov. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAMEH BOLES/

Examiner, Art Unit 3775